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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,052	09/10/2003	Laura C. Blumberg	PC10770B	7289

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PFIZER INC.
PATENT DEPARTMENT, MS8260-1611
EASTERN POINT ROAD
GROTON, CT 06340

EXAMINER

BERNHARDT, EMILY B

ART UNIT PAPER NUMBER

1624

DATE MAILED: 12/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/660,052

Applicant(s)

BLUMBERG ET AL.

Examiner

Emily Bernhardt

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10, 11 and 20-33 is/are pending in the application.
- 4a) Of the above claim(s) 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10, 11, 20, 22-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

In view of applicants' response filed 9/27/04 the following applies.

Applicants' election of Group I subject matter with traverse is acknowledged but is not persuasive. Applicants appear to traverse the restriction solely because the examiner has not demonstrated that the fields of search are diverse. Applicants are requested to recheck the restriction requirement of the previous action in which a comprehensive but by no means complete classification of various groups was given as well as additional reasons for the propriety of the restriction requirement.

Accordingly, the restriction is deemed proper and is therefore made FINAL.

This application contains claim 21 drawn to an invention nonelected with traverse in Paper filed 9/27/04. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 10 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Reason #5 of the previous action is maintained. It is recognized that in Tuominen the issue was a 102 rejection but the point is that if the composition claims having only different intended uses are the same for prior art purposes, they must also be the same for 112 purposes. See Tuominen at right column at p.89, beginning line of last paragraph. Applicant urges that the claims embrace different amounts but this is not consistent with the specification which teaches the same dosage ranges regardless of use. See p.47.

Claims 10,11,20 and 22-33 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The traverse to this rejection is not persuasive for the following reasons. Simply asserting that the entire genus has CCR1 activity does not automatically avoid an enablement rejection. If it did, the factors discussed in *In re Wands* and the MPEP would not have to be evaluated. Given the many factors that do pertain in the instant case as discussed in previous actions there is reason to question efficacy of the instant scope given the **homogeneity** of the prepared examples coupled with the lack of any test data (just an inference that compounds were tested). As there is no test data reported and thus

no structure-activity trends that can be evaluated more than undue experimentation is required to determine which permutations out of the billions claimed might be suitable to practice the invention. Thus, the examiner has not limited an analysis of the Wands factors to just one factor but rather many and based on the deficiencies that exist for most has considered "the evidence as a whole" weighing against enablement. A recent Board decision, namely, *Ex parte Varshavsky* in 63 USPQ2d 1486, decided that a high level of skill in the art was not sufficient to override other Wands factors that demonstrated undue experimentation for the **full** scope claimed.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 10,11,20 and 23 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Bauman for reasons of record. Applicants first state that prior art compound pointed out in Bauman does not read on the instant claims. True, but the instant rejection was not under 102 but rather 103. Novelty does not negate obviousness. The moiety "alkoxycarbonylalkylaminoalkyl" is still present as a choice for R5 and it only differs from the species previously pointed out in lacking the "carbonyl" in the middle of the complex moiety. Instant moiety is included as a preferred embodiment from a list that is no more (but probably less) encompassing than applicants' scope and follows the moiety which is exemplified

as species in col.37, lines 28-30. See preferred choices in col.28 in US Bauman. Thus the motivation to make the necessary changes comes from the prior art's preferred embodiments which includes a structurally close species. Compare with In re Burckel 201 USPQ 67 or In re Lamberti 192 USPQ 278 or In re Mills 176 USPQ 196. Applicants' additional comment regarding the lack of a teaching of criticality (suitability) of substituent's choices in Bauman is not consistent with their own specification's lack of test data and limited species (presumably tested) vs. scope claimed which includes a majority of moieties not made much less shown to possess the requisite activity needed to practice the invention. While "obvious to try" is not deemed a proper standard for a rejection under 103, obviousness does not require absolute predictability of success only reasonable expectation of success as stated in In re O'Farrell 7 USPQ 2d 1073 (at p.1081). Given the close similarity in structure with Bauman's compounds that only differ at **one position** off a sidechain phenyl ring and have the same activity as urged herein, the rejection is being maintained.

Applicants' Terminal Disclaimer has been approved and thus the obviousness double patenting rejection over parent is overcome.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Bernhardt whose telephone number is 571-272-0664.

If attempts to reach the examiner by telephone are unsuccessful, the acting supervisor for AU 1624, James O. Wilson can be reached at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Application/Control Number: 10/660,052
Art Unit: 1624

Page 7

A handwritten signature in cursive script, appearing to read "Emily Bernhardt".

Emily Bernhardt
Primary Examiner
Art Unit 1624